No. 96-188

IN THE
Supreme Court of the United States
OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION,
and MONSANTO COMPANY,
Petitioners,

v.

ROBERT K. JOINER and KAREN P. JOINER,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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BRIEF OF THE AMERICAN MEDICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTIONS PRESENTED

Amicus curiae will address the following questions:

Whether an appellate court should defer to the exercise by a district court of its discretion to exclude proffered expert scientific testimony that did not meet the test of admissibility set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

Whether, in exercising its discretion under Rule 702 of the Federal Rules of Evidence as construed in *Daubert*, the district court may consider the substance of proffered expert testimony to determine whether that testimony has sufficient scientific support to be of assistance to the trier of fact.

TABLE OF CONTENTS

	Page
QUESTIONS PRESENTED	i
TABLE OF AUTHORITIES	iv
INTEREST OF *AMICUS CURIAE*	1
STATEMENT	3
SUMMARY OF ARGUMENT	5
ARGUMENT	7
I. DISTRICT COURT DECISIONS EXCLUDING EXPERT TESIMONY, LIKE OTHER EVIDENTIARY RULINGS, SHOULD BE REVERSED ONLY IF THE DISTRICT COURT ABUSED ITS DISCRETION	7
II. DISTRICT COURTS MUST REVIEW THE SUBSTANCE OF PROFFERED EXPERT TESTIMONY IN ORDER TO DETERMINE WHETHER IT IS SCIENTIFICALLY VALID AND PROPERLY APPLICABLE TO THE CASE	9
III. A TRIAL COURT DOES NOT USURP THE DUTIES OF THE TRIER OF FACT BY ADMITTING ONLY EXPERT OPINIONS WITH A SOUND SCIENTIFIC BASIS	15
IV. THE ADMISSION OF "EXPERT" OPINIONS THAT DO NOT HAVE SOUND SCIENTIFIC SUPPORT HAS AN ADVERSE EFFECT ON PHYSICIANS, THEIR PATIENTS, AND SOCIETY	17
CONCLUSION	21

TABLE OF AUTHORITIES

CASES

	Page
Amore v. G.D. Searle & Co., 748 F. Supp. 845 (S.D. Fla. 1990)	18
Claar v. Burlington N. R.R., 29 F.3d 499 (9th Cir. 1994)	16
Cummins v. Lyle Indus., 93 F.3d 362 (7th Cir. 1996)	8
Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311 (9th Cir.), *cert. denied*, 116 S. Ct. 189 (1995)	13
Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993)	*passim*
Diemer v. Cincinnati Sub-Zero Prods., Inc., 58 F.3d 341 (7th Cir. 1995)	7
Duffee v. Murray Ohio Mfg. Co., 91 F.3d 1410 (10th Cir. 1996)	5, 7
E.I. du Pont de Nemours & Co. v. Robinson, 923 S.W.2d 549 (Tex. 1995)	13
Eichel v. New York Cent. R.R., 375 U.S. 253 (1963)	9
Hamling v. United States, 418 U.S. 87 (1974)	5, 7
Joy v. Bell Helicopter Textron, Inc., 999 F.2d 549 (D.C. Cir. 1993)	8
Low v. United States, 795 F.2d 466 (5th Cir. 1986)	19
Nemmers v. United States, 612 F. Supp. 928 (C.D. Ill. 1985), *vacated on other grounds*, 795 F.3d 628 (7th Cir. 1986)	19
Raynor v. Merrell Pharm. Inc., 104 F.3d 1371 (D.C. Cir. 1997)	7
Stillwell & Bierce Mfg. Co. v. Phelps, 130 U.S. 520 (1889)	7
United States v. Abel, 469 U.S. 45 (1984)	8
United States v. Dorsey, 45 F.3d 809 (4th Cir.), *cert. denied*, 115 S. Ct. 2631 (1995)	7
United States v. Sepulveda, 15 F.3d 1161 (1st Cir. 1993), *cert. denied*, 512 U.S. 1223 (1994)	8, 9

RULES

Fed. R. Evid. 102	17
Fed. R. Evid. 104(a)	9

TABLE OF AUTHORITIES—Continued

	Page
Fed. R. Evid. 702	6, 8, 17
Fed. R. Evid. 703	6, 13
Fed. R. Evid. 704	17
Fed. R. Evid. 705	17

OTHER AUTHORITIES

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B. Ames & L. Gold, *Chemical Carcinogenesis: Too Many Rodent Carcinogens*, 87 Proceedings of the National Academy of Science 7772 (Oct. 1990)	15
M. Angell, *Science on Trial* (1996)	11, 12, 16
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K. Foster, D. Bernstein & P. Huber, *Phantom Risk: Scientific Inference and the Law* (1994)	11
S.E. Gabriel *et al.*, *Risk of Connective-Tissue Diseases and Other Disorders After Breast Implantation*, 330 New Eng. J. Med. 1697 (1994)	11
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C. H. Hennekens *et al.*, *Self-Reported Breast Implants and Connective Tissue Diseases in Female Health Professionals*, 275 JAMA 616 (1996)	11

TABLE OF AUTHORITIES—Continued

	Page
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J. Neale & R. Liebert, *Science and Behavior: An Introduction to Methods of Research* (1980)	10
K. Popper, *The Logic of Scientific Discovery* (1959)	10
A. Relman, *Publishing Biomedical Research: Rules and Responsibilities*, Hastings Center Rep. 23 (May/June 1990)	11
J. Sanchez-Guerrero *et al.*, *Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms*, 332 New Eng. J. Med. 1666 (1995)	11
J. Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301 (1992)	18
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U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services* (2d ed. 1996)	14

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BRIEF OF THE AMERICAN MEDICAL ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTEREST OF *AMICUS CURIAE*

Amicus American Medical Association (AMA) is a private, voluntary, nonprofit organization of physicians. The AMA was founded in 1847 to promote the science and art of medicine and the improvement of the public health. Its nearly 300,000 members practice in all fields of medicine.

The AMA believes that physicians have an ethical obligation to assist in the administration of justice. This obligation includes the duty to assist in securing a patient's legal rights and in providing relevant and reliable testi-

mony to assist the trier of fact in making decisions. See AMA, *Code of Medical Ethics* § 9.07 (see *infra*, note 5). At the same time, the AMA opposes testimony that (a) is not based on sound scientific or medical research, or (b) is not probative of the point in support of which it is offered. Such testimony serves to prolong meritless litigation and to mislead factfinders. It can have an immediate and lasting impact on the price and availability of physician services, pharmaceuticals, medical devices, and other products.

The AMA is, of course, sympathetic to respondent Joiner for having to endure the ordeal of cancer. As an organization of physicians, the AMA understands full well the awful effects of this horrible disease—both on those whom it afflicts and on their families. But sympathy for the Joiners, and indeed for any sufferer of disease, should not induce courts to make judgments about the cause of disease on the basis of anything less than relevant and reliable scientific evidence.

Reliance by juries on flawed medical or scientific testimony can best be minimized by requiring expert evidence to be methodologically sound, scientifically valid, and properly applicable to the facts of a given case. Expert conclusions based on poor science, or on any science that does not adequately support the conclusion proffered by the testifying expert, should be excluded. Determinations regarding the admissibility of proposed scientific or medical evidence are best made by the trial court, assisted when the court deems it useful, by an independent scientific expert appointed pursuant to Rule 706 of the Federal Rules of Evidence. Decisions excluding expert testimony, like other evidentiary determinations, should be reversed only for abuse of discretion.

The more stringent standard of review adopted by the court below would deter district courts from exercising their gatekeeper responsibilities as articulated by this Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,

509 U.S. 579 (1993). A district court must have discretion to determine whether the scientific evidence relied upon by a proposed expert adequately supports the conclusions to which the expert would testify. Accordingly, *amicus* American Medical Association urges that the judgment of the court of appeals be reversed and that this case be remanded for consideration of whether the district court acted within its discretion in excluding the testimony of respondents' experts.[1]

STATEMENT

Amicus adopts the statement of the case as set forth by petitioners in their brief in this Court and emphasizes the following facts:

1. Respondents relied primarily upon the testimony of two expert witnesses to support their claim that Mr. Joiner's lung cancer, although likely caused by tobacco smoke, was promoted by his workplace exposure to polychlorinated biphenyls (PCBs). Pet. App. 39a. One expert testified that his medical practice focused on persons involved in litigation. J.A. 104, 109, 126-27. The other expert stated that he testifies three to four times per month, "almost always" for the plaintiff. J.A. 167-69.

2. The district court identified several independent grounds for holding that respondents' expert testimony was not admissible to prove causation. Most significantly, the court concluded that respondents' experts lacked an adequate scientific foundation for their conclusion that exposure to PCBs promoted Mr. Joiner's lung cancer.

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[1] Pursuant to Rule 37.6 of the Rules of this Court, *amicus* states that no counsel for a party authored this brief in whole or in part, and that no person or entity other than *amicus* and its counsel made any monetary contribution to the preparation or submission of this brief. Pursuant to Rule 37.3 of the Rules of this Court, the parties have consented to the filing of this brief. The parties' letters of consent have been filed with the Clerk of the Court.

Pet. App. 53a, 59a-62a.[2] In particular, the court held that valid scientific conclusions could not be drawn as to whether occupational exposure to limited concentrations of PCBs could promote lung cancer in humans where the only scientific evidence used to support these conclusions consisted of two studies in which infant mice were injected with high concentrations of PCBs. Pet. App. 59a-62a.

3. The court of appeals identified several factors in concluding that the judgment of the district court failed to withstand what the Eleventh Circuit characterized as the "particularly stringent standard of review" applicable to a trial judge s exclusion of expert testimony. Pet. App. 4a. First, the court of appeals emphasized the fact that respondents' witnesses possessed expert credentials and were familiar with the case. Pet. App. 8a-11a. The court stated that the mere fact of their expertise "augment[ed] the reliability of the reasoning of their methodology." Pet. App. 11a. Second, the court accepted without apparent question the general assertions of these experts that their reasoning conformed to sound scientific practice. Pet. App. 9a-10a. Third, the court of appeals held that, in determining whether an expert's opinion is "legally unreliable," the district court may not consider whether that opinion can validly be drawn from the scientific evidence upon which the expert relies. Pet. App. 11a-13a. Fourth, rather than considering the scientific evidence cited by an expert to support a conclusion, the court held that "the bases of an expert's opinion" must be considered "as a whole" to determine "legal reliability." Pet. App. 13a.

In a special concurrence, Judge Birch emphasized the value of appointing an independent expert, pursuant to Rule 706 of the Federal Rules of Evidence, to assist the court in "evaluating the reliability of the proffered expert

[2] *Amicus* expresses no opinion as to the methodology or validity of any of the studies upon which the experts based their opinions.

evidence." Pet. App. 17a. In dissent, Judge Smith observed that "[i]t is incumbent on the proponent of scientific evidence to fill the analytical gap between a proffered study and the particular facts of the case" and that the trial court "may properly request good grounds to bridge the gap before admitting the testimony." Pet. App. 26a.

SUMMARY OF ARGUMENT

The judgment of the court of appeals should be reversed and the case remanded for that court to determine whether the district court properly exercised its discretion in excluding the testimony of respondents' experts.

I. The court of appeals erred in applying "a stringent standard of review to the trial judge's exclusion of expert testimony." Pet. App. 4a. Determinations regarding the admissibility of evidence in general, and expert testimony in particular, have long rested within the sound discretion of the district court. *Hamling v. United States*, 418 U.S. 87, 108 (1974). Nothing in this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), changed that standard. To the contrary, *Daubert* repeatedly stressed the flexible nature of the inquiry necessary to determine whether expert testimony is grounded in valid science and is properly applicable to the facts of the case. *Id.* at 589, 593, 594 & n.12. "Daubert requires district judges to act as gatekeepers to ensure that scientific evidence is both relevant and reliable . . . . Their decisions, therefore, are properly reviewed under the traditional abuse of discretion standard." *Duffee v. Murray Ohio Mfg. Co.*, 91 F.3d 1410, 1411 (10th Cir. 1996).

II. The substantive criteria applied by the Eleventh Circuit are inconsistent with *Daubert* and would prevent district courts from excluding proffered evidence that is scientifically unreliable or not probative of the question at issue. The court of appeals limited its focus to the general credentials of respondents' witnesses, their asser-

tions that they had adhered to scientific method, and their citation of various studies in support of their opinions. See Pet. App. 10a-13a.

However, to determine whether proffered expert evidence is built on scientifically valid reasoning and methodology that "properly can be applied to the facts in issue," *Daubert*, 509 U.S. at 593, the trial court must examine the substance of the proposed testimony. Specifically, the court must make a preliminary assessment as to whether the research used to support the expert's testimony was conducted in accordance with scientific method and supportive of the expert's conclusion. The district court must consider whether the conclusions to which the expert would testify can, as a matter of good science, be drawn from scientifically-generated data. See Fed. R. Evid. 703. Unsound science and unfounded speculation by scientists should not be admitted into evidence. Such speculation will not "assist the trier of fact." Fed. R. Evid. 702.

III. Allowing district courts to consider the substance of proffered expert testimony in applying the *Daubert* criteria will not, as the court of appeals feared, "turn judges into jurors or surrogate scientists." Pet. App. 7a. A district court may not choose between competing theories when both have sound scientific support. Nor may the court exclude a scientifically supported theory that has yet to achieve widespread acceptance in the scientific community. *Daubert*, 509 U.S. at 594.

It is nevertheless the responsibility of the court to distinguish between subjects of legitimate scientific disagreement on one hand and invalid science on the other. The proper way to discharge this responsibility is to examine the substance of an expert's evidence to determine whether it is (a) predicated on scientifically valid reasoning and methodology and (b) properly applied to the facts at issue. Adequate resources are available to assist judges in making these determinations. Most significantly,

Rule 706 of the Federal Rules of Evidence authorizes the appointment of independent experts to assist the court —an option that district courts should exercise with greater frequency.

IV. Giving trial courts the latitude to consider the substance of an expert's testimony also serves important policy objectives. Legal judgments based upon expert opinions not developed in accordance with scientific methodology have caused manufacturers to withdraw from the market a number of drugs and devices found by the Food and Drug Administration to be safe and effective. Such legal judgments also have stymied innovation in pharmaceutical and vaccine research and caused physicians to discontinue providing certain services. The withdrawal of beneficial products and medical services has a serious and entirely unwarranted adverse effect on public health. Allowing district courts to exclude unsound scientific testimony will promote the factfinding function of the legal process and simultaneously avoid doing violence to the values that undergird science.

ARGUMENT

I. DISTRICT COURT DECISIONS EXCLUDING EXPERT TESTIMONY, LIKE OTHER EVIDENTIARY RULINGS, SHOULD BE REVERSED ONLY IF THE DISTRICT COURT ABUSED ITS DISCRETION.

This Court has repeatedly stated that "the District Court has wide discretion in its determination to admit and exclude evidence, and this is particularly true of expert testimony." *Hamling v. United States*, 418 U.S. 87, 108 (1974). See *Stillwell & Bierce Mfg. Co. v. Phelps*, 130 U.S. 520, 527 (1889). Accordingly, district court decisions admitting or excluding expert testimony have been reviewed with deference. See *Raynor v. Merrell Pharm. Inc.*, 104 F.3d 1371, 1374 (D.C. Cir. 1997); *Duffee*, 91 F.3d at 1411; *Diemer v. Cincinnati Sub-Zero Prods., Inc.*, 58 F.3d 341, 344 (7th Cir. 1995); *United States v. Dorsey*, 45 F.3d 809, 813-14 (4th Cir.), *cert. denied*, 115 S.

Ct. 2631 (1995); *United States v. Sepulveda*, 15 F.3d 1161, 1183 (1st Cir. 1993), *cert. denied*, 512 U.S. 1223 (1994).

Nothing in the language of Rule 702 of the Federal Rules of Evidence indicates an intention to depart from this well-established principle of common law. See generally *United States v. Abel*, 469 U.S. 45, 50-51 (1984) (considering common law in interpreting the Rules of Evidence where the common law precept is consistent with the Rules), *quoted in Daubert*, 509 U.S. at 587-88. The Rule makes no reference to appellate review standards and imposes no specific limitation on the authority of the trial court. It simply provides that an expert may testify "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue . . . ." Fed. R. Evid. 702.

Similarly, nothing in the *Daubert* opinion indicates an intention to apply a heightened standard of appellate review to decisions concerning the admissibility of expert testimony. To the contrary, *Daubert* emphasizes the relationship between Rule 702 and other Rules of Evidence, including Rules 403 and 703. See 509 U.S. at 595. Decisions under these rules are reversed only for an abuse of discretion. See, *e.g.*, *Abel*, 469 U.S. at 54 (Rule 403); *Cummins v. Lyle Indus.*, 93 F.3d 362, 371 (7th Cir. 1996) (Rule 703).[3]

[3] The court of appeals' justification for its "particularly stringent" standard of review lacks merit. Pet. App. 4a. The Eleventh Circuit believed that a heightened standard of review is required because "the Federal Rules of Evidence governing expert testimony display a preference for admissibility . . . ." Pet. App. 4a. In fact, the Federal Rules do not display such a preference. Rather, Rule 402 states a preference for admissibility of "relevant evidence." A preference for admissibility of relevant evidence does not bespeak a heightened standard of appellate review. Relevance rulings are reversed only for an abuse of discretion. *See Abel*, 469 U.S. at 54; *Joy v. Bell Helicopter Textron, Inc.*, 999 F.2d 549, 554 (D.C. Cir. 1993).

Indeed, continued use of a deferential standard of appellate review is implicit in the criteria for determining the admissibility of scientific expert evidence set forth in *Daubert*. To make a meaningful determination as to whether proffered expert testimony is scientifically reliable and properly applicable to the facts of a case, the district court must make preliminary factual determinations, often after an evidentiary hearing. See Fed. R. Evid. 104(a) (authorizing the trial court to make preliminary evidentiary determinations unbounded by the rules of evidence (except those concerning privileges)). The *Daubert* opinion stresses the flexible nature of this inquiry. 509 U.S. at 594-95. See also *id.* at 593 ("Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test").

The district court possesses a superior vantage point from which to evaluate the evidence. See *Eichel v. New York Cent. R.R.*, 375 U.S. 253, 256 (1963) (Harlan, J., concurring in part and dissenting in part); *Sepulveda*, 15 F.3d at 1183. The standard of review should reflect the fact that the district court is better situated to make admissibility determinations. Here, by contrast, the Eleventh Circuit afforded no deference whatsoever to the evidentiary determinations by the district court. The judgment of the court of appeals should therefore be vacated and the case remanded with instructions to review the judgment of the district court under an abuse of discretion standard.

II. DISTRICT COURTS MUST REVIEW THE SUBSTANCE OF PROFFERED EXPERT TESTIMONY IN ORDER TO DETERMINE WHETHER IT IS SCIENTIFICALLY VALID AND PROPERLY APPLICABLE TO THE CASE.

In addition to applying the incorrect standard of review, the court of appeals improperly limited the factors that may be considered by a district court in determining the

admissibility of expert testimony. This error was based on the Eleventh Circuit's erroneous conclusion that "the Federal Rules of Evidence governing expert testimony display a preference for admissibility." Pet. App. 4a. Quite to the contrary, "*Daubert* clearly requires trial judges to subject expert evidence to more penetrating pretrial scrutiny." American College of Trial Lawyers, *Standards and Procedures for Determining the Admissibility of Expert Evidence After Daubert*, 157 F.R.D. 571 (1994). Specifically, a district court must make "a preliminary assessment of [A] whether the reasoning or methodology underlying the testimony is scientifically valid and [B] whether that reasoning or methodology can be applied to the facts in issue." *Daubert*, 509 U.S. at 592-93. A mere assertion by a proffered expert that proposed testimony is based on good science is not a sufficient basis for allowing that expert to present conclusions to the jury.

A. To determine whether expert testimony has a sound scientific foundation, the trial court must determine whether the proffered expert testimony rests on knowledge acquired through the scientific method. *Daubert*, 509 U.S. at 590. This method involves empirical or other systematic testing of a hypothesis. See generally National Academy of Sciences *et al.*, 1 *Responsible Science: Ensuring the Integrity of the Research Process* 36-40 (1992); K. Popper, *The Logic of Scientific Discovery* (1959).

The scientist must collect and analyze data using rigorous and replicable techniques. J. Neale & R. Liebert, *Science and Behavior: An Introduction to Methods of Research* 7, 14 (1980). Peer reviewers must be able to analyze the study and identify potential flaws in the techniques, data, and statistical or other methods employed. Research that satisfies the rigors of peer review should provide some assurance that the specific conclusion drawn from that study is "scientific." *Responsible Science*, at 55-56. Scientists, through peer-reviewed publication, explain to the scientific community precisely how data

were collected and analyzed, and the extent to which specific hypotheses are supported by the available evidence. A. Relman, *Publishing Biomedical Research: Rules and Responsibilities*, Hastings Center Rep. at 23 (May/June 1990).

Open disclosure, critical review, and skepticism are hallmarks of the scientific process. Scientific knowledge grows only through continual questioning and criticism. Results of individual studies add to a base of scientific knowledge that accumulates incrementally over time. The process is tedious, rigorous, and slow. However, the integrity of science demands this process to ensure that perceptions, speculations, and untested theories do not become accepted as scientific truths. See K. Foster, D. Bernstein & P. Huber, *Phantom Risk: Scientific Inference and the Law* 19 (1994).

Experts who purport to offer conclusions that cannot be substantiated by research are not relying on science. For example, this practice has occurred in some silicone-gel breast implant cases. Plaintiffs in these cases have asserted that they suffer a variety of connective tissue diseases as a consequence of their exposure to the silicone-gel in their implants. However, several well-designed (albeit not conclusive) epidemiological studies have not demonstrated a clear link between silicone-gel breast implants and heightened risk of connective tissue disease. See M. Angell, *Science on Trial* 27, 100-03 (1996).[4]

In response, some putative experts have shifted the emphasis in their testimony and asserted that silicone-gel

[4] The key studies cited by Dr. Angell are: S.E. Gabriel *et al.*, *Risk of Connective-Tissue Diseases and Other Disorders After Breast Implantation*, 330 New Eng. J. Med. 1697 (1994); C.H. Hennekens *et al.*, *Self-Reported Breast Implants and Connective Tissue Diseases in Female Health Professionals*, 275 JAMA 616 (1996); J. Sanchez-Guerrero *et al.*, *Silicone Breast Implants and the Risk of Connective-Tissue Diseases and Symptoms*, 332 New Eng. J. Med. 1666 (1995).

breast implants cause various undefined diseases. The association posited by these experts cannot be formulated as a hypothesis and cannot be tested empirically. *Id.* at 108-09. Therefore, to assert that such an association exists is not science; it is rank speculation. Witnesses should not be permitted to present such speculative testimony to juries simply because they are qualified as experts in a particular field.

Similarly, evidence by experts who have effectively become advocates for a viewpoint or for one side in a controversy (such as respondents' experts in this case) should be viewed with particular skepticism. Good science is independent and unbiased. It is undertaken in order to add to the store of medical or scientific knowledge—not to muster support for a predetermined position in litigation. For this reason, the American Medical Association's Code of Medical Ethics provides that a "medical witness must not become an advocate or a partisan" in a legal proceeding or accept compensation "contingent upon the outcome of litigation." AMA, *Code of Medical Ethics* § 9.07.[5]

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[5] Opinion 9.07, entitled "Medical Testimony," provides:

> As a citizen and as a professional with special training and experience, the physician has an ethical obligation to assist in the administration of justice. If a patient who has a legal claim requests a physician's assistance, the physician should furnish medical evidence, with the patient's consent, in order to secure the patient's legal rights.
>
> Medical experts should have recent and substantive experience in the area in which they testify and should limit testimony to their sphere of medical expertise. Medical witnesses should be adequately prepared and should testify honestly and truthfully to the best of their medical knowledge.
>
> The medical witness must not become an advocate or a partisan in the legal proceeding. The attorney for the party who calls the physician as a witness should be informed of all favorable and unfavorable information developed by the physician's evaluation of the case. It is unethical for a physician to accept compensation that is contingent upon the outcome of litigation.
>
> AMA, *Code of Medical Ethics* § 9.07 (issued June 1986, updated June 1996).

"[W]hen an expert prepares reports and findings before being hired as a witness, that record will limit the degree to which he can tailor his testimony to serve a party's interests." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir.) (on remand), *cert. denied*, 116 S. Ct. 189 (1995). Research conducted and opinions formed "solely for the purpose of testifying are more likely to be biased toward a particular result." *E.I. du Pont de Nemours & Co. v. Robinson*, 923 S.W.2d 549, 559 (Tex. 1995). A court should be reluctant to admit purported expert testimony that relies on such evidence absent other sources of scientific corroboration.

B. In addition to being grounded in good scientific methodology, expert evidence must properly be applicable to the particular case. *Daubert*, 509 U.S. at 591-92 ("Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility"). To meet this requirement in cases involving scientific evidence, the underlying data must be sufficient to support the conclusion that the testifying expert intends to present to the jury. In other words, the data must be "of a type reasonably relied upon by experts in the particular field in forming opinions and inferences upon the subject. . . ." Fed. R. Evid. 703. In determining whether the data upon which an expert relies provide a scientifically sound foundation for the expert's proffered testimony, a trial court should consider both the nature of the study and the type of conclusions that it will support.

1. Scientific data can be gathered in a number of ways. Differences in the type of study and the size and composition of the database affect the nature and strength of conclusions that can be drawn. For instance, epidemiological

evidence is of greater scientific value than anecdotal observation.[6] Epidemiological studies gather a greater range of data and therefore can better account for chance occurrences and other variables that might unexpectedly affect results. Moreover, epidemiological data can be reviewed and replicated by other scientists so that conclusions can be confirmed.[7] In contrast, anecdotal evidence makes no effort to control for variables that might affect a database.

2. Scientific studies designed to address only limited issues do not support far-reaching conclusions on causation. Scientific knowledge grows only through continual questioning and criticism. Results of individual studies add to a base of scientific knowledge that accumulates incrementally over time. Indeed, some scientifically valid studies do no more than suggest subjects for future research.

While a study may produce a narrow finding that would be of interest in a particular field of research, it may not support broad conclusions with respect to causation. An expert witness should not be allowed to testify to such conclusions based on an inadequate scientific foundation. Such testimony would not be based on scientific knowledge and would not comport with scientific method. Rather, the expert would be engaging in precisely the sort of speculation forbidden by *Daubert*.

In the present case, respondents' experts relied on two studies in which infant mice injected with high concentrations of PCBs developed cancer. Animal studies may, in some circumstances, provide strong support for a scientific

[6] *See generally* U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services* 1 (2d ed. 1996) (ranking different types of clinical studies to give greater evidentiary weight to "study designs that are, in general, less subject to bias and misinterpretation").

[7] Even one well-designed epidemiological study may have more scientific weight than another because, statistically, a higher confidence level can be assigned to its results. *Daubert*, 509 U.S. at 594.

conclusion.[8] However, if the two studies of mice described above constituted the only evidence presented in support of the conclusion that PCB exposure promotes a specific type of lung cancer in humans, that conclusion should not be admitted in evidence. The differences between humans and mice, as well as the route and dose of PCB exposure, are so great that it is not scientifically sound to extrapolate to the more general conclusion that occupational exposure to PCBs promoted respondent's specific type of lung cancer.

III. A TRIAL COURT DOES NOT USURP THE DUTIES OF THE TRIER OF FACT BY ADMITTING ONLY EXPERT OPINIONS WITH A SOUND SCIENTIFIC BASIS.

The Eleventh Circuit gave two reasons for barring district courts from examining the substantive support for expert evidence. First, the court expressed concern that such an approach would require judges to act as scientists. Second, the court warned that such substantive consideration would usurp the duties of the trier of fact. Pet. App. 7a-8a, 11a-12a. Both concerns are misplaced.

A. Judges are routinely called upon to determine whether there is an adequate foundation for testimony and to exclude testimony that lacks such support. They perform precisely the same function in determining whether there is an adequate scientific foundation for expert testimony.

[8] The extrapolation of experimental results from animals to humans is controversial. Although positive findings in animals may be suggestive, the results are not necessarily equivalent to findings in humans. This is particularly true when significant discrepancies occur between animal and human exposures in terms of dose, route of administration, and physiological responses. To fill data gaps, scientists look to evidence from epidemiological studies of exposed and nonexposed populations. Ultimately, making a determination of cause and effect requires studies from multiple scientific disciplines such as biochemistry, molecular biology, genetics, toxicology, and epidemiology. *See* B. Ames & L. Gold, *Chemical Carcinogenesis: Too Many Rodent Carcinogens*, 87 Proceedings of the National Academy of Science 7772 (Oct. 1990).

Many of these determinations can be made simply as a matter of common sense.[9] The mice study example presented above is such a case. It should be apparent that studies in which infant mice developed cancer after being injected with high doses of PCBs do not, taken alone, support a reasoned scientific conclusion that occupational exposure to minute quantities of PCBs promotes a specific type of lung cancer in humans.

Moreover, the Federal Rules of Evidence provide a specific mechanism for making expert assistance available to trial judges. Rule 706 provides that the court may on its own motion appoint an independent expert witness to advise the court on whether the scientific analysis underlying an expert's proffered testimony is consistent with good scientific practices. Rule 706 has rarely been invoked by trial court judges. *Amicus* submits, however, that increased use of the process envisaged by Rule 706 will assist judges in fulfilling their role as gatekeepers by distinguishing between good science and speculation dressed up to pass as science. See generally *Science on Trial* at 205.

B. The judge, acting as a gatekeeper of proffered scientific evidence, does not encroach on the authority of the jury. *Amicus* is not proposing the exclusion of minority views of scientific evidence or suggesting that judges choose between competing scientific theories. Rather, *amicus* urges only that judges require proponents of expert testimony to demonstrate that the testimony has a sound scientific basis. See *Claar v. Burlington N. R.R.*, 29 F.3d 499, 501 (9th Cir. 1994) (court may inquire "into the reliability of the methods and reasoning underlying the conclusions" in the proposed testimony).

Expert witnesses have a special status under the Federal Rules of Evidence. They need not testify from per-

[9] Other issues can be resolved by reference to the *Reference Manual on Scientific Evidence* prepared by the Federal Judicial Center.

sonal knowledge and the basis for their opinions need not be admissible. Fed. R. Evid. 705. Moreover, experts, unlike other witnesses, generally may opine on the "ultimate issues" to be decided by the jury. Fed. R. Evid. 704.

Partially in recognition of the special status of experts and the special risks their testimony engenders, Rule 702 establishes a higher standard than mere relevance for the admissibility of expert testimony, especially testimony by scientific experts. See *Daubert*, 509 U.S. at 592. The evidence must "assist the trier of fact." Fed. R. Evid. 702. Expert testimony that purports to offer scientific conclusions when the underlying research is flawed or does not support the conclusions proffered, does nothing to assist the trier of fact. Speculation—even speculation by someone with scientific credentials—is still only speculation. What is worse, the expert's testimony is speculation cloaked in the garb of seemingly impressive academic credentials. The risk that this speculation will be considered by the trier of fact as entitled to more weight than common sense would dictate is why the trial court's role as a gatekeeper is so vital.

IV. THE ADMISSION OF "EXPERT" OPINIONS THAT DO NOT HAVE SOUND SCIENTIFIC SUPPORT HAS AN ADVERSE EFFECT ON PHYSICIANS, THEIR PATIENTS, AND SOCIETY.

In addition to the plain language of Rule 702, sound public policy counsels that district courts have the latitude to exclude expert testimony that offers conclusions lacking in scientific support. The introduction of evidence not grounded in scientific knowledge may, of course, lead to inequitable judgments in individual cases. *Cf.* Fed. R. Evid. 102 (the Federal Rules of Evidence should be construed to further the goal of ascertaining the truth and providing a just determination of a case). But, even more fundamentally, permitting civil damage actions to be decided on the basis of opinions not grounded in science

will, over time, have a detrimental effect on patients and on society generally.

Examples from recent history demonstrate that, as a result of legal judgments based upon invalid medical or scientific opinions, medical professionals and their patients have been deprived of a number of beneficial treatment options. Bendectin is a prime example of a beneficial drug, approved as "safe and effective" by the Food and Drug Administration, that is no longer available to physicians and patients because of liability imposed on the basis of unscientific expert testimony.[10]

Similarly, the FDA still considers the Copper-7 intrauterine device ("IUD") to be "safe and effective."[11] However, a number of federal courts have allowed experts to offer opinions without basis in scientific methodology suggesting that this IUD is far more dangerous than any legitimate study has demonstrated. See, *e.g.*, *Amore v. G.D. Searle & Co.*, 748 F. Supp. 845 (S.D. Fla. 1990). Although the manufacturer prevailed in a number of cases alleging injury based upon the use of this IUD, see *id.* at 848 n.3, by 1986, it became impossible to purchase insurance for the product.[12]

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[10] More than 30 scientific studies have been conducted to determine whether any statistically significant correlation exists between the use of this drug and limb defects. No study has demonstrated such a correlation. *See* J. Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301 (1992) (summarizing the findings).

[11] Use of this IUD involves a very slight risk of pelvic inflammatory disease.

[12] The adverse impact of unfounded liability has "contributed significantly to the climate of disincentives for the development of contraceptive products." National Research Council & Institute of Medicine, *Developing New Contraceptives—Obstacles and Opportunities* 141 (L. Mastroianni *et al.* eds., 1990). "In the early 1970s, there were 13 pharmaceutical companies actively pursuing research in contraception and fertility. Now, only one US company conducts contraceptive and fertility research." AMA Board of Trustees,

The admission of unscientific testimony also has affected the availability of many vaccines. All but one manufacturer stopped making the vaccine for diphtheria, tetanus, and pertussis (whooping cough) following a series of lawsuits based upon expert "opinion" that the pertussis portion of the vaccine might in fact be causing encephalopathy (an inflammatory brain disease). See J. Cherry, *"Pertussis Vaccine Encephalopathy": It Is Time to Recognize It as the Myth That It Is*, 263 JAMA 1679 (1990). Thorough epidemiological studies have demonstrated that there is no statistically significant relationship between the vaccine and encephalopathy. See M. Griffin *et al.*, *Risk of Seizures and Encephalopathy After Immunization With the Diphtheria-Tetanus-Pertussis Vaccine*, 263 JAMA 1641 (1990).

Unscientific judgments also have directly affected the provision of medical services. In particular, many obstetricians have been subject to successful tort claims attributing various ailments, including cerebral palsy, to their improper handling of deliveries and their failure to perform cesarean sections.[13] See, *e.g.*, *Low v. United States*, 795 F.2d 466 (5th Cir. 1986); *Nemmers v. United States*, 612 F. Supp. 928 (C.D. Ill. 1985), *vacated on other grounds*, 795 F.3d 628 (7th Cir. 1986). The available scientific evidence, however, provides no support for the hypothesis that cerebral palsy results from improper delivery techniques.[14]

Impact of Product Liability on the Development of New Medical Technologies, at 9 (June 1988).

[13] Soaring malpractice premiums for obstetricians and family physicians who practice obstetrics have driven many such physicians out of that practice, especially in rural areas. *See* American College of Obstetricians and Gynecologists, *Professional Liability Insurance and Its Effects; Report of a Survey of ACOG's Membership* (1992).

[14] Indeed, it is increasingly clear that obstetricians have virtually no ability to prevent cerebral palsy through either the use of

In short, the admission of unscientific medical "opinion" furthers no legitimate scientific, legal, or social purpose. To the contrary, if opinions that lack a scientific foundation are admitted into evidence, then some judgments inevitably will be based on those opinions. And, as a result, the practice of medicine will be influenced by these judgments, to the detriment of the health of the public. Such a perverse result is at odds with the goals of the Federal Rules of Evidence and of the judicial process itself, and makes the law the enemy of good science.

Rule 702 does not require such harmful consequences. To the contrary, the Rule's language and structure evince an intent to promote the truth-finding process both inside and outside the courtroom by requiring expert opinion to be based on scientifically accepted methods. District courts should be allowed to exercise their discretion under Rule 702 to exclude testimony that is based on bad science or that proffers conclusions that cannot be supported based on available scientific data.

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electronic fetal monitoring devices or more frequent cesarean sections. *See* K. Shy *et al., Effects of Electronic Fetal-Heart-Rate Monitoring, as Compared with Periodic Auscultation, on the Neurologic Development of Premature Infants*, 322 New Eng. J. Med. 588 (1990).

CONCLUSION

The judgment of the court of appeals should therefore be reversed.

Respectfully submitted,

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